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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,442

02/26/2004

Julia E. Novak

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09/29/2006

ZYMOGENETICS, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
1201 EASTLAKE AVENUE EAST  
SEATTLE, WA 98102-3702

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647.

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/787,442

Applicant(s)

NOVAK ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, drawn to a fusion protein comprising a first polypeptide of SEQ ID NO: 2 and comprising a second cytokine polypeptide of SEQ ID NO: 111, classified in class 530, subclass 350.
  - II. Claims 1-2, drawn to a fusion protein comprising a first polypeptide of SEQ ID NO: 2 and comprising a second cytokine polypeptide of SEQ ID NO: 112, classified in class 530, subclass 350.
  - III. Claims 1-2, drawn to a fusion protein comprising a first polypeptide of SEQ ID NO: 2 and comprising a second cytokine polypeptide of SEQ ID NO: 113, classified in class 530, subclass 350.
  - IV. Claims 1-2, drawn to a fusion protein comprising a first polypeptide of SEQ ID NO: 2 and comprising a second cytokine polypeptide of SEQ ID NO: 114, classified in class 530, subclass 350.
  - V. Claims 3-5, drawn to a fusion protein comprising four cytokine polypeptide fragments, classified in class 530, subclass 350.
  - VI. Claims 6-9, drawn to a fusion protein comprising a polypeptide of SEQ ID NO: 2 and immunoglobulin heavy chain constant region, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

- a. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 802.01, MPEP § 806.06). In the instant case, the different inventions of Groups I-VI are unrelated product and method, wherein each is not required, one for another. The different inventions of Groups I-VI are not obvious polypeptide variants.

Rather, each fusion polypeptide is a unique amino acid sequence, requiring a unique search of the prior art. Each fusion polypeptide may have unique and diverse functional feature. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different classification and different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

2. The claims of Group V are drawn to multiple fusion proteins as evidenced by their sequences comprising four polypeptides selected from:

- (i) amino acid residues from 41-56 of SEQ ID NO: 2;
- (ii) IL-2 helix B residues 53-75 of SEQ ID NO: 111;
- (iii) IL-4 helix B residues 65-83 of SEQ ID NO: 112;
- (iv) IL-15 helix B residues 84-101 of SEQ ID NO: 113;
- (v) GMCSF helix B residues 72-81 of SEQ ID NO: 114;
- (vi) amino acid residues from 69-84 of SEQ ID NO: 2;
- (vii) IL-2 helix C residues 87-99 of SEQ ID NO: 111;
- (viii) IL-4 helix C residues 95-118 of SEQ ID NO: 112;
- (ix) IL-15 helix C residues 107-119 of SEQ ID NO: 113;
- (x) GMCSF helix C residues 91-102 of SEQ ID NO: 114;
- (xi) amino acid residues from 92-105 of SEQ ID NO: 2;
- (xii) IL-2 helix D residues 101-121 of SEQ ID NO: 111;
- (xiii) IL-4 helix D residues 134-157 of SEQ ID NO: 112;
- (xiv) IL-15 helix D residues 134-160 of SEQ ID NO: 113;
- (xv) GMCSF helix D residues 120-131 of SEQ ID NO: 114;
- (xvi) amino acid residues from 135-148 of SEQ ID NO: 2;

Art Unit: 1647

- (xvii) IL-2 helix A residues 36-46 of SEQ ID NO: 111;
- (xviii) IL-4 helix A residues 29-43 of SEQ ID NO: 112;
- (xix) IL-15 helix A residues 45-68 of SEQ ID NO: 113;
- (xx) GMCSF helix A residues 30-44 of SEQ ID NO: 114;
- (xxi) amino acid residues from 41-56 of SEQ ID NO: 2;
- (xxii) amino acid residues from 135-148 of SEQ ID NO: 2.

Each of the different sequences are independent and distinct because they contain distinct amino acid structures. Accordingly, these sequences are each subject to restriction under 35 U.S.C. § 121. Applicant is additionally required to elect four amino acid sequence fragments which comprise the fusion polypeptide, which if determined to be patentable, would also be patentably distinct from the other amino acid sequences. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

4. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

Art Unit: 1647

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
Art Unit 1647,  
September 19, 2006

*Jegatheesan Seharaseyon*  
—  
*Patent Examiner*